510(k) SUMMARY: K130274

[As required by 21CFR807.92]

OCT 29 2013

ELITE SURGICAL SUPPLIES (PTY) LTD

Contact detail

510(k) Summary – Biolign Intervertebral Cages	
Prepared	September 11, 2013
Name of firm	Elite Surgical Supplies (Pty) Ltd. 184 Bessemer Road, Pretoria-West Industrial 0183 South Africa
Postal Address	P.O. Box 26115 Arcadia Pretoria 0007 South Africa
510(k) Contact	Rudi Verbeek Technical Director and Regulatory Affairs Tel: +27 12 386 0012 Facsimile: +27 12 386 2745 Email: rudi@elitesurgical.com
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Product detail

Biolign® Transforaminal Lumbar Intervertebral Fusion (TLIF) device	
Classification	21 CFR 888.3080 Intervertebral body fusion device Class II (Special Controls) Orthopaedic and Rehabilitation Devices Panel (87) Product Code MAX (Intervertebral body fusion device with bone graft, Lumbar).
Predicates	Spinecraft ORIO-TL - K090887
Device Description	The Biolign TLIF device is a slightly curved cage manufactured from Invibio PEEK Optima LT1 with cavities which can be packed with autograft. The cage has tantalum markers which allow accurate and correct placement of the device. The cage is postero-laterally inserted. The cage incorporates a threaded introducer hole on each end and has serrated inferior and superior endplates. It is available in two footprints (30x13mm, and 36x13mm), two lordotic angles (5° and 10°), and a range of heights ranging from 6 – 12mm with 1mm intervals These sizing options allow selection for individual pathology and anatomical conditions. The device is used with supplemental fixation such as screw and rod systems. The Biolign® TLIF system is provided sterile.. The System is single use only.
Indications for use	The Biolign® Tlif Interbody Fusion Devices are indicated for use with autograft bone graft in skeletally mature patients with degenerative disc disease (DDD) at one level or two contiguous levels of the lumbar spine (L2 - S1). DDD is defined as backpain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The DDD patients may also have up to Grade I spondylolisthesis at the involved level(s). These patients should be skeletally mature and have six (6) months of non-operative therapy. The Biolign® TLIF Intervertebral fusion devices are used to facilitate fusion in the lumbar spine and are implanted via a postero-lateral approach. The Biolign® intervertebral fusion devices are intended to be used with supplemental fixation systems that have been cleared for use in the lumbosacral spine for example posterior pedicle screw and rod systems.
Comparison of the device to the predicate	Elite Surgical Supplies' Biolign® TLIF Spacer is substantially equivalent to the predicates in design, function, performance, material, sterilization and intended use.

device(s)	
Performance data (Non-Clinical)	Elite Surgical Supplies conducted the following bench testing as recommended by FDA guidances and in accordance with ASTM 2077 and ASTM 2267: Static and Dynamic axial compression, Static shear compression, torsion testing and subsidence testing. Results drawn from the testing performed, as well as from an engineering rationale, demonstrate that the Biolign TLIF spacer is substantially equivalent in performance to the predicate device.
Performance data (Clinical)	Clinical data and conclusions were not needed for this device.

Biolign® Anterior Cervical Interbody Fusion (ACIF) System	
Classification	21 CFR 888.3080 Intervertebral body fusion device Class II (Special Controls) Orthopaedic and Rehabilitation Devices Panel (87) Product Code ODP (Intervertebral body fusion device with bone graft, Cervical).
Predicates	AMT Shell Cervical cage- K080401
Device Description	The Biolign ACIF device is an anatomically correct cage manufactured from Invibio PEEK Optima LT1 with a central cavity which can be packed with autograft. The cage is available in two footprints (15 and 17mm) with a 10° lordotic angle. Cage heights range from 6mm-10mm with 1mm intervals. These sizing options allow selection for individual pathology and anatomical conditions. Tantalum radiographic markers enable clear x-ray control during placement and follow-up. The cage endplates are serrated. The Device is inserted below the anterior surface of the cervical vertebrae. It is used with supplemental cervical plating systems which have prominence from the spine (plate thickness). The Biolign® ACIF system is provided sterile The System is for single use only.
Indications for use	The Biolign® ACIF System is indicated for use as an intervertebral body fusion device in skeletally mature patients with degenerative disc disease at one level from C3-C7. Cervical disc disease is defined as discogenic pain with degeneration of the disc confirmed by history and radiographic studies. Patients should have six (6) weeks of non-operative treatment. The Biolign® ACIF System is to be used with autograft bone graft and is implanted via an open anterior approach. The Biolign® ACIF System is intended to be used with supplemental fixation systems that have been cleared for in the cervical spine, such as Anterior Cervical plating systems.
Comparison of the device to the predicate	Elite Surgical Supplies' Biolign® ACIF Spacer is substantially equivalent to the predicates in design, function, performance, material, sterilization and intended use.

device(s)	
Performance data (Non-Clinical)	Elite Surgical Supplies conducted the following bench testing as recommended by FDA guidances and in accordance with ASTM 2077: Static axial compression, Static shear compression, and static torsion testing. Results drawn from the testing performed, as well as from an engineering rationale, demonstrate that the Biolign ACIF spacer is substantially equivalent in performance to the predicate device.
Performance data (Clinical)	Clinical data and conclusions were not needed for this device.

	Biolign® Stand Alone Cervical Cage (STACC) ACIF System
Classification	21 CFR 888.3080 Intervertebral body fusion device Class II (Special Controls) Orthopaedic and Rehabilitation Devices Panel (87) Product Code OVE (Intervertebral fusion device with integrated fixation, cervical).
Predicates	Surgicraft Ltd Stalif - K072415
Device Description	The Biolign® STACC ACIF Interbody Fusion Device is a stand-alone device and does not rely on additional fixation such as cervical plates. The device is an anatomically shaped ring, with a central cavity which can be packed with autograft. It is manufactured of Invibio Peek Optima LT1. Two Tantalum pins are placed in the device to enable radiographic visualization for placement and follow-up evaluations. The superior, and inferior endplates of the device are serrated. Two fixation screws per cage are used as supplemental fixation. These screws are placed into the cage and purchase into the vertebral endplates. The fixation screws are manufactured of Titanium 6Al4V ELI. The footprint of the cage is available in one size (17 x 14mm), and in heights ranging from 5.5 - 9.5mm with 1mm intervals. The cage is available in a domed (superior endplate is domed, and inferior endplate has 3° lordosis angle) and a tapered version (8° lordosis – 4° per endplate) The device is implanted using an anterior approach and after implantation does not stand prominent from the cervical spine. It lies below the anterior surface of the cervical spine. The Biolign® STACC ACIF system is supplied sterile. The System is for single use only.
Indications for use	The Biolign® STACC ACIF System is indicated for use as an intervertebral body fusion device in skeletally mature patients with degenerative disc disease at one level from C3-C7. Cervical disc disease is defined as discogenic pain with degeneration of the disc confirmed by history and radiographic studies. Patients should have

	six (6) weeks of non-operative treatment. The Biolign® STACC ACIF System is to be used with autograft bone graft and is implanted via an open anterior approach. The Biolign STACC ACIF system is intended to be used as a stand-alone system using the bone screws provided for fixation. It may also be used with supplemental fixation system that have been cleared for use in the cervical spine, such as cervical plating systems.
Comparison of the device to the predicate device(s)	Elite Surgical Supplies' Biolign® STACC Spacer is substantially equivalent to the predicates in design, function, performance, material, sterilization and intended use.
Performance data (Non-Clinical)	Elite Surgical Supplies conducted the following bench testing as recommended by FDA guidances and in accordance with ASTM 2077: Static and dynamic axial compression, Static shear compression, and static and dynamic torsion testing, screw push-out testing, tension offset testing, and impact testing. Results drawn from the testing performed, as well as from an engineering rationale, demonstrate that the Biolign STACC spacer is substantially equivalent in performance to the predicate device.
Performance data (Clinical)	Clinical data and conclusions were not needed for this device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

October 29, 2013

Elite Surgical Supplies (Pty) Limited
Mr. Rudi Verbeek
Technical Director
P.O. Box 26115
Arcadia
Pretoria
0007 South Africa

Re: K130274
Trade/Device Name: Biolign® ACIF System
Biolign® STACC ACIF System
Biolign® TLIF Intervertebral Body Fusion Device
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: OVE, MAX, ODP
Dated: September 11, 2013
Received: September 25, 2013

Dear Mr. Verbeek:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Erin D Keith

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: December 31, 2013
See PRA Statement on last page.

510(k) Number *(if known)*
K130274

Device Name
Biolign® ACIF System

Indications for Use *(Describe)*
The Biolign® ACIF System is indicated for use as an intervertebral body fusion device in skeletally mature patients with degenerative disc disease at one level from C3-C7. Cervical disc disease is defined as discogenic pain with degeneration of the disc confirmed by history and radiographic studies. Patients should have six (6) weeks of non-operative treatment. The Biolign® ACIF System is to be used with autograft bone graft and is implanted via an open anterior approach. The Biolign® ACIF System is intended to be used with supplemental fixation systems such as Anterior Cervical plating systems.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Anton E. Dmitriev, PhD
Division of Orthopedic Devices

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: December 31, 2013
See PRA Statement on last page.

510(k) Number *(if known)*
K130274

Device Name
Biolign® TLIF Intervertebral Body Fusion Device

Indications for Use *(Describe)*
The Biolign® TLIF Intervertebral Body Fusion Devices are indicated for use with autograft bone graft in skeletally mature patients with degenerative disc disease (DDD) at one level or two contiguous levels of the lumbar spine (L2 - S1).

DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The DDd patients may also have up to Grade I spondylolisthesis at the involved level(s). These patients should be skeletally mature and have six (6) months of non-operative therapy.

The Biolign® TLIF Intervertebral Body Fusion Devices are used to facilitate fusion in the lumbar spine and are implanted via a postero-lateral approach.

The Biolign® Intervertebral Body Fusion Devices are intended to be used with supplemental fixation systems that have been cleared for use in the lumbosacral spine, for example posterior pedicle screw and rod systems.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

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Anton E. Dmitriev, PhD
Division of Orthopedic Devices

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: December 31, 2013
See PRA Statement on last page.

510(k) Number *(if known)*
K130274

Device Name
Biolign® STACC ACIF System

Indications for Use *(Describe)*
The Biolign® STACC ACIF System is indicated for use as an intervertebral body fusion device in skeletally mature patients with degenerative disc disease at one level from C3-C7. Cervical disc disease is defined as discogenic pain with degeneration of the disc confirmed by history and radiographic studies. Patients should have six (6) weeks of non-operative treatment. The Biolign® STACC ACIF System is to be used with autograft bone graft and is implanted via an open anterior approach. The Biolign® STACC ACIF system is intended to be used as a stand-alone system using the bone screws provided for fixation. It may also be used with supplemental fixation systems that have been cleared for use in the cervical spine, such as cervical plating systems.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

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